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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/209,961	12/10/98	WANG	9000-0040

HM22/0121

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EXAMINER	
SALIMI, A	

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 01/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/209,961	Wang et al
Examiner	**Group Art Unit**
ALI R. SALIMI	1645

☒ Responsive to communication(s) filed on *Nov 15, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *Three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-47* is/are pending in the application.

Of the above, claim(s) *1-6, 10, 11, 15, 16, 20, 21, and 25-47* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7-9, 12-14, 17-19, and 22-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4, 5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Claims 1-47 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Election/Restriction

Applicant's election with traverse of Group II (claims 7-9, 12-14, 17-19, 22-24) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Applicants believe the examination of all groups is not unduly burdensome . This is not found persuasive because considering the separate classification and divergent search requirements of the distinct groups, it is maintained that examination of all groups would be unduly burdensome. Clearly different searches and issues are involved in the examination of each group, especially with respect of the percent identity limitations, derived fragments and immunogenic constructs, various sequence searches and different gap and default calculations need to be considered, both in the in house and commercial data bases.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 10, 11, 15, 16, 20, 21, 25-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups, the requirement having been traversed in Paper No. 7.

Applicant is reminded to cancel the claims to the non elected claims.

Specification

The disclosure is objected to because of the following: The date and the designated accession number for the deposited virus are missing from the specification page 8, lines 29, and 30. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7-9 are vague and indefinite, the claims are very confusing. The metes and bounds of the derived polypeptide(s) is/are not defined. The intended derived polypeptide should be identified. Is a nucleic acid encoding five amino acid long and polypeptide having 85% identity of the said five amino acids intended? For example, SEQ ID NO: 3 is 314 amino acids long which translates into 942 nucleotides, what are the metes and bounds of polypeptides that are derived

from SEQ ID NO: 3. In addition, the term "at least about" is unclear. Is about intended? Moreover, the metes and bounds of the intended fragments are not defined. This affects the dependent claims.

Claims 17-19 are confusing, does this read on gene therapy or DNA vaccines? Is induction of immune response intended? The claims have been interpreted in light of the specification, and since the specification does not have clear teaching as to what is intended the claims are hereafter objected to. Is the transformation, *in vivo*, or *in vitro*? This affects the dependent claims.

Claim Rejections - 35 USC § 112

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of antibody response, does not reasonably provide enablement for transformation of cells in inducing a protective response (vaccine). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The scope of the claims read on transformation of the host cell which reads on a vaccine development. Applicants are reminded that the field of vaccine development is considered to be highly unpredictable. According to the specification and the state of the art the currently claimed virus attacks the immune system and disables the immune response. A vaccine

is considered to be protective wherein upon re- introduction of the disease to induce a long lasting protective response against a challenge. The current specification does not teach nor enables a vaccine to induce a protective response wherein upon introduction of the specific antigens or fragments thereof in to a host a protective response can be inferred. Absent teaching by the specification it would require undue experimentation for one ordinary skill in the art to enable the scope of the claims. The specification provides no teaching as to the transformation and induction of immunogenic protective response against the claimed antigenic fragments. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meehan et al (J of Gen. Virology, 1997, vol. 78, pp. 221-227).

The polypeptide and the nucleotide sequence disclosed by the above cited article meets the limitations of the claimed invention. In addition it also meets the limitations of derived and fragments. The above cited art meets the limitations of 85% identity, and immunogenic fragments of 5 at least about five amino acids, of the claimed limitation. Alternatively, it would have been obvious to one ordinary skill in the art to derive polypeptides from the disclosed sequence and utilize the fragments to enhance immune response. The ordinary skilled artisan being familiar with the state of the art and the cited article would not have anticipated any unexpected results. The claims are deemed ***prima facie*** obvious absent unexpected results.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meehan et al (J of Gen. Virology, 1997, vol. 78, pp. 221-227) and Vogel et al (Clinical Microbiology Review, 1995, Vol. 8, No. 3, pp. 406-410).

The claims are directed to polynucleotide encoding an immunogenic polypeptide of circovirus Type II (PCVII), in addition to nucleotides having 85% identity to the polypeptides derived form various ORFs. In addition, the claims are directed to recombinant vector expressing the various polypeptide fragments derived from the said ORFs wherein the expression construct is derived by a foreign promoter. Furthermore, the claims are directed to host cells transformed by an expression vector encoding PCVII nucleotide to induce an immune response.

Meehan et al disclosed the complete nucleotide sequence of porcine circovirus. They further disclosed the genomic organization of the PCV genome (see the abstract, and page 223, right paragraph). This differs since they did not teach a vector and expression of the nucleic acids.

Vogel et al disclosed the use of DNA vaccines wherein a nucleic acid sequences is encoded within a vector with a heterologous promoter present to ensure high level of expression (see page 406, column 2, paragraph 2, and Figure 1). This differs since they did not teach the circovirus genome.

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated by the above teaching to incorporate the nucleotide fragment sequences derived from the circovirus taught by Meehan et al into a vector taught by Vogel et al to transform the host cell

in inducing an immunogenic response in a host. In addition, the utilization of vector in a method of producing polypeptide in cell culture is considered to be routine in this art. The skilled artisan being familiar with the genomic organization and nucleotide sequence of the said virus would not have anticipated any unexpected results. Thus, the invention as a whole is considered to be prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

1/19/2000

ALI SALIMI
PATENT EXAMINER